K000492

JUN - 7 2000

510(k) SUMMARY

MDA® D-Dimer

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and the final rule under 21 CFR 807.92 published December 14, 1994.

(a) (1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

Submitter's Name:	Organon Teknika Corporation
Submitter's Address:	100 Akzo Avenue, Durham, North Carolina 27712, USA
Submitter's Telephone:	(919) 620-2373
Submitter's Fax:	(919) 620-2548
Submitter's Contact:	Ron Sanyal, M. Pharm, CQE, RAC
Date 510(k) Summary Prepared:	February 7, 2000

(a) (2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

Trade/Proprietary Name:	MDA® D-Dimer
Common/ Usual Name:	Fibrin Degradation Product
Classification Name:	Fibrin Degradation Product

(a) (3) **An identification of the legally marketed device to which the submitter claims substantial equivalence.**

Device Equivalent to: 1. MDA® D-Dimer (K974776)

(a) (4) **A description of the device(System)**

Organon Teknika's **MDA® D-Dimer** is a homogeneous latex particle based immunoassay for the quantitative determination of cross-linked fibrin degradation products containing the D-dimer domain in citrated human plasma.

D-dimer containing fibrin degradation products (FbDP) fragments are released when cross-linked fibrin is degraded by plasmin. Cross-linked fibrin is formed when fibrionogen is cleaved by thrombin to form fibrin monomers, which then spontaneously polymerize and are cross-linked by Factor XIIIa. Thrombin is required to cleave fibrinogen as well as to activate Factor XIII. Plasmin formation is triggered when a fibrin clot is formed. Plasmin degrades some of the cross-linked fibrin and the resulting level of D-dimer is, therefore, an indirect measure of thrombin generation and subsequent clot formation.

D-dimer is elevated in disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), pulmonary embolism (PE), sickle cell crisis, pre-eclampsia, some cause of unstable angina, myocardial infarction, some cancers, and following major surgery or trauma.

MDA® D-Dimer is a quantitative homogeneous-phase immunoassay using latex microparticles to photo-optically detect binding of specific monoclonal antibody to D-dimer. These latex particles aggregate in the presence of fibrin derivatives containing the D-dimer domain. The rate of latex microparticle aggregation is proportional to the concentration of D-dimer in the sample. D-dimer concentration may be interpolated from a reference curve.

(a) (5) **A statement of the intended use of the device.**

Device Intended Use: **MDA® D-Dimer** is a homogeneous latex particle based immunoassay for the quantitative determination of cross-linked fibrin degradation products containing the D-dimer domain in citrated human plasma. MDA D-Dimer can be used to aid in the assessment and evaluation of patients suspected of venous thromboembolism (VTE), which is comprised of deep vein thrombosis (DVT) and pulmonary embolism (PE). The assay is designed for use on the MDA automated coagulation analyzers.

(a) (6) **A summary of the technological characteristics of the new device in comparision to those of the predicate device.**

The technological characteristics of the device **MDA® D-Dimer** in comparison to those of the 510(k) cleared device **MDA® D-Dimer assay (K974776)** are given in the table 1 below.

Table 1

Category	MDA® D-Dimer assay (K974776)	MDA® D-Dimer
Medical Device	Yes	Yes
Intended Use	**MDA® D-Dimer** is a homogeneous latex particle based immunoassay (LIA) for the quantitative determination of cross-linked fibrin degradation products containing the D-dimer domain in citrated human plasma. The assay is designed for use on the MDA® automated coagulation analyzers.	**MDA® D-Dimer** is a homogeneous latex particle based immunoassay for the quantitative determination of cross-linked fibrin degradation products containing the D-dimer domain in citrated human plasma. MDA D-Dimer can be used to aid in the assessment and evaluation of patients suspected of venous thromboembolism (VTE), which is comprised of deep vein thrombosis (DVT) and pulmonary embolism (PE). The assay is designed for use on the MDA automated coagulation analyzers.
Regulatory Class	Class II	Class II
Product Code	DAP, GHH	DAP, GHH
Classification Panel	Hematology	Hematology
C.F.R. Section	21 CFR 864.7320	21 CFR 864.7320
Presentation	Automated Latex Immunoassay	Automated Latex Immunoassay
Format	Quantitative	Quantitative
Instrument	MDA® automated coagulation analyzers	MDA® automated coagulation analyzers
Reagents	Same	Same
Principle of the procedure	Same	Same
Quality Control	Same	Same
Test Procedure	Same	Same
Reference Curve Range	0-4.0 µg FEU/ml	0-4.0 µg FEU/ml

(b) (1) **A brief discussion of the nonclinical tests submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Not Applicable

(b)(2) **A brief discussion of the clinical tests submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Comparison Data:

Performance Characteristics

Specificity

MDA D-Dimer Latex Reagent aggregates in the presence of cross-linked fibrin degradation products D-dimer and D-dimer E.

Accuracy

Results from **MDA D-Dimer** reagents obtained on an MDA were compared with a commercially available assay (Fibrinostika® FbDP EIA)for detection of crosslinked and non–crosslinked fibrin degradation product containing the D-dimer. Specimens were tested in duplicate according to NCCLS Approved Guideline EP9-A.[29] The following results for slope, intercept and correlation were observed for linear least squares regression comparing **MDA D-Dimer** (y-axis) and the reference method (x-axis):

Reference Method	n	Slope	Intercept	r
Fibrinostika® FbDP EIA	175	1.005	0.293	0.91

Precision

Total precision and within-run precision for the **MDA D-Dimer** assay were determined in accordance with NCCLS Tentative Guideline EP5-T2.[30] Controls were tested in duplicate on an MDA instrument twice daily. Data were collected for 20 days, with a minimum of 40 runs and 80 measurements at each control level. The following precision was observed:

Sample	Mean (µg FEU/ml)	SD (within-run) (µg FEU/ml)	CV (within-run) (%)	SD(total) (µg FEU/ml)	CV(total) (%)
Positive Control	1.51	0.06	3.83	0.10	6.67
MDA Verify 1 (Normal Control)	0.28	0.02	6.97	0.04	12.65

(b) (3) **The conclusion drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a) (3).**

In conclusion, the MDA® D-Dimer has successfully met all aspects of non-clinical and clinical testing and have demonstrated that the device is safe and effective and has performed well and is substantially equivalent to the legally marketed device **MDA® D-Dimer assay (K974776).**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 7 2000

Mr. Ron Sanyal, M. Pharm, CQE, RAC
Regulatory Affairs Administrator
Organon Teknika Corporation
100 Akzo Avenue
Durham, North Carolina 27712

Re: K000492
Trade Name: MDA® D-Dimer Assay
Regulatory Class: II
Product Code: DAP
Dated: April 26, 2000
Received: April 27, 2000

Dear Mr. Sanyal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): K000492

Device Name: MDA® D-Dimer

Indications For Use:

MDA® D-Dimer is a homogeneous latex particle based immunoassay for the quantitative determination of cross-linked fibrin degradation products containing the D-dimer domain in citrated human plasma. MDA D-Dimer can be used to aid in the assessment and evaluation of patients suspected of venous thromboembolism (VTE), which is comprised of deep vein thrombosis (DVT) and pulmonary embolism (PE). The assay is designed for use on the MDA automated coagulation analyzers.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter S Makin

(Division Sign Off)
Division of Clinical Laboratory Devices
510(k) Number K000492

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)